REMARKS

Claims 1-108 were examined.

Claims 1-108 were rejected.

Claims 1-4, 11, 13-17, 21-26, 33-41, 49-52, 54-57, 65-66, 68-75, 83-85, 88-89, 92-95 and 103 have been amended and claims 7, 27 and 42 have been canceled.

Claims 1-6, 8-26 and 28-108 are pending after the entry of the amendments made herein.

Claim 1 has been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test, based on the measured flow rate of physiological fluid at the site. Support for these amendments may be found in the specification, for example at page 7, paragraph [0025], page 22, paragraph [0088], pages 32 and 33, paragraphs [00123] and [00124], and Figure 1.

Claim 11 has been amended to replace "sample" with "fluid" where antecedent basis for physiological fluid is found in claim 1 from which it depends.

Claim 16 has been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the at least one physiological fluid sample type characterization element determines whether a site includes arterial fluid, venous fluid or interstitial fluid. The claim has also been amended to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test, based on the determined fluid type. Support for these amendments may be found in the specification, for example at page 7, paragraph [0025], page 12, paragraphs [0039], page 22, paragraph [0088], pages 32 and 33, paragraphs [00123] and [00124], and Figure 1.

Claim 36 has been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test, based on the measured flow rate of physiological fluid at the site and based on the determined type of fluid at the site. Support for these amendments may be found in the specification, for example at page 7, paragraph [0025], page 12, paragraphs [0039], page 22, paragraph [0088], pages 32 and 33, paragraphs [00123] and [00124], and Figure 1.

Claim 49 has been amended to specify that the method is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test, based on the measured flow rate of physiological fluid at the site. Support for these amendments may be found in the specification, for example at page 7, paragraph [0025], page 22, paragraph [0088], and Figure 1.

Claim 65 has been amended to specify that the method is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test, based on the determined fluid type. Support for these amendments may be found in the specification, example at page 7, paragraph [0025], page 22, paragraph [0088], and Figure 1.

Claim 68 has been amended to depend from claim 67.

Claim 83 has been amended to specify that the method is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test, based on the measured flow rate of physiological fluid and based on the determined fluid type at the site. Support for these amendments may be found in the specification, example at page example at page 7, paragraph [0025], page 12, paragraphs [0039], page 22, paragraph [0088], and Figure 1.

Claims 1-4, 11, 13-17, 21-26, 33-41, 49-52, 54-57, 65-66, 68-75, 83-85, 88-89, 92-95 and 103 have been amended to clarify the invention.

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow claims 1-6, 8-26 and 28-41, and 43-108, the only claims pending in this application.

As no new matter has been added by the above amendments, the Applicants respectfully request the entry thereof.

REJECTION UNDER 35 U.S.C. §112 SECOND PARAGRAPH

Claims 11, 27, 65 and 68 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 has been amended to replace "sample" with "fluid". Antecedent basis for physiological fluid is found in claim 1 from which it depends. Claim 27 has been cancelled. Claim 65 has been amended to remove reference to "said flow characterization" and to specify that the determining step includes determining whether the determined potentially suitable site is suitable for the analyte concentration determination test based on the determined fluid type. Claim 68 has been amended to depend from claim 67, which provides proper antecedent basis for the subject matter of claim 68. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §102(e)

Claims 1, 6, 7, 12-14, 16, 21, 32-34, 49, 53-55, 58, 59, 65-67, 68, 73, 76, 77, 83, 87-91, 96 and 97 under 35 U.S.C. §102(e) as being anticipated by Yamazaki. Claim 7 has been cancelled.

Claim 1, and claims 6, 12-14 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate of physiological fluid at the site. However, Yamazaki fails to teach either a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test or means as claimed in these claims. For at least these reasons, Yamazaki does not teach all of the claimed limitations of claims 1, 6, and 12-14.

Claim 16, and claims 21, 32, 33 and 34 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, that the at least one physiological fluid sample type characterization element determines whether a site includes arterial fluid, venous fluid or interstitial fluid, and also that the device includes means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Yamazaki fails to teach a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, a physiological fluid sample type characterization element that determines whether a site includes arterial fluid, venous fluid or interstitial fluid or means as claimed in these claims. For at least these reasons, Yamazaki does not teach all of the claimed limitations of claims 16, 21 and 32-34.

Claim 49, and claims 53-55, 58 and 59 that depend therefrom, have been amended to specify that the method is for determining the suitability of a site for sampling physiological fluid for use in an

analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate. However, Yamazaki does not teach a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, nor does Yamazuki teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in the an analyte concentration determination test based on a measured flow rate. For at least these reasons, Yamazaki does not teach all of the claimed limitations of claims 49, 53-55, 58 and 59.

Claim 65, and claims 66, 67, 68, 73, 76 and 77 that depend therefrom, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a determining step that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on determined fluid type. However, Yamazuki fails to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Yamazuki fails to teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in the an analyte concentration determination test based on the determined fluid type. For at least these reasons, Yamazaki does not teach all of the claimed limitations of claims 65, 66, 67, 68, 73, 76 and 77.

Claim 83, and claims 87-91, 96 and 97 that depend therefrom, have been amended to specify that the method is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate of physiological fluid at the site and based on the determined fluid type at the site. However, Yamazuki fails to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Yamazuki fails to teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate of physiological fluid at the site and based on the determined fluid type at the site. For at least these reasons, Yamazaki does not teach all of the claimed limitations of claims 83, 87-91, 96 and 97.

Accordingly, for at least the reasons described above, Yamazuki does not teach all of the claimed limitations of claims 1, 6, 12-14, 16, 21, 32-34, 49, 53-55, 58, 59, 65-67, 68, 73, 76, 77, 83, 87-91, 96 and 97. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 36, 37, 39, 40, 42, 83 and 86 were rejected under 35 U.S.C. §102(e) as being anticipated by Toida et al. Claim 42 has been cancelled.

Claim 36, and claims 37, 39, and 40 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the flow rate of physiological fluid at the site and based on the type of fluid at the site. However, Toida et al. fail to teach a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test or means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the flow rate of physiological fluid at the site and based on the type of fluid at the site. For at least these reasons, Toida et al. do not teach all of the claimed limitations of claims 36, 37, 39 and 40.

Claim 83, and claim 86 that depends therefrom, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on measured flow rate of physiological fluid at the site and based on the determined fluid type at the site. However, Toida et al. fail to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Toida et al. fail to teach a method that includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on measured flow rate of physiological fluid at the site and based on the determined fluid type at the site. For at least these reasons, Toida et al. do not teach all of the claimed limitations of claims 83and 86.

Accordingly, for at least the reasons described above, Toida et al. do not teach all of the claimed limitations of claims 36, 37, 39, 40, 83 and 86. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 1, 2, 7, 12, 13, 16, 27, 32 and 33 were rejected under 35 U.S.C. §102(b) as being anticipated by Barker. Claims 7 and 27 have been cancelled.

Claims 1, and claims 2, 12 and 13 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate at the site. However, Barker fails to teach either a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test or means as claimed in these claims. For at least these reasons, Barker does not teach all of the claimed limitations of claims 1, 2, 12 and 13.

Claim 16, and claims 32 and 33 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, that the at least one physiological fluid sample type characterization element determines whether a site includes arterial fluid, venous fluid or interstitial fluid, and also that the device includes means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Barker fails to teach a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, a physiological fluid sample type characterization element that determines whether a site includes arterial fluid, venous fluid or interstitial fluid or means as claimed in these claims. For at least these reasons, Barker does not teach all of the claimed limitations of claims 16, 32 and 33.

Accordingly, for at least the reasons described above, Barker does not teach all of the claimed limitations of claims 1, 2, 12, 13, 16, 32 and 33. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 1, 3-5, 7, 12, 13, 15-18, 22, 27, 32, 33, 35, 49, 51, 52, 57-59, 65, 69, 73, 75-77, 83, 85, 86, 92, 96 and 97 were rejected under 35 U.S.C. §102(b) as being anticipated by Tiemann et al. Claims 7 and 27 have been cancelled.

Claim 1, and claims 3-5, 12, 13, and 15 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an

analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate of physiological fluid at the site. However, Tiemann et al. fail to teach either a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test or means as claimed in these claims. For at least these reasons, Tiemann et al. do not teach all of the claimed limitations of claims 11, 3-5, 12-13 and 15.

Claim 16, and claims 17, 18, 22, 32, 33 and 35 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, that the at least one physiological fluid sample type characterization element determines whether a site includes arterial fluid, venous fluid or interstitial fluid, and also that the device includes means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Tiemann et al. fail to teach a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, a physiological fluid sample type characterization element that determines whether a site includes arterial fluid, venous fluid or interstitial fluid or means as claimed in these claims. For at least these reasons, Tiemann et al. do not teach all of the claimed limitations of claims 16, 17, 18, 22, 32, 33 and 35.

Claim 49, and claims 51, 52, 55, 57-59 that depend therefrom, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate. However, Tiemann et al. do not teach a method for sampling physiological fluid for use in an analyte concentration determination test, nor do Tiemann et al. teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate. For at least these reasons, Tiemann et al. do not teach all of the claimed limitations of claims 49, 51, 52, 55, and 57-59.

Claim 65, and claims 69, 73 and 75-77 that depend therefrom, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a determining step that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Tiemann et al. fail to

teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on determined fluid type. For at least these reasons, Tiemann et al. do not teach all of the claimed limitations of claims 65, 69, 73 and 75-77.

Claim 83, and claims 85, 86, 92, 96 and 97 that depend therefrom, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate of physiological fluid and based on the determined fluid type at the site. However, Tiemann et al. fail to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate of physiological fluid and based on the determined fluid type at the site. For at least these reasons, Tiemann et al. do not teach all of the claimed limitations of claims 83, 85, 86, 92, 96 and 97.

Accordingly, for at least the reasons described above, Tiemann et al. do not teach all of the claimed limitations of claims 1, 3-5, 12, 13, 15-18, 22, 32, 33, 35, 49, 51, 52, 57-59, 65, 69, 73, 75-77, 83, 85, 86, 92, 96 and 97. As such, the Applicants respectfully request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §103(a)

Claims 16 and 27-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over Douglas et al. Claim 27 has been cancelled.

As described above, claim 16, and claims 28-30 that depend therefrom, have been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, that the at least one physiological fluid sample type characterization element determines whether a site includes arterial fluid, venous fluid or interstitial fluid, and also that the device includes means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Douglas et al. do not teach or suggest such a device. Douglas describes a device for sampling and analyzing body fluid. Douglas et al. do not teach or even suggest that the device

determines the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Douglas et al. fail to teach or even suggest a device that includes a physiological fluid sample type characterization element that determines whether a site includes arterial fluid, venous fluid or interstitial fluid. Still further, Douglas et al. fail to teach or even suggest means for determining whether the site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the determined fluid type.

For at least the reasons described above, Tiemann et al. do not teach or suggest all of the claimed limitations of claims 16 and 28-30. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 8-10, 61, 63, 79, 81, 99 and 101 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Douglas et al.

Claim 1, from which claims 8- 10 depend, have been amended to specify a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate of physiological fluid at the site. However, Tiemann et al. is generally directed to an apparatus for characterizing tumor tissue and do not to teach or even suggest a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, as Tiemann et al. is concerned with tumor tissue characterization, Tiemann et al. do not teach or suggest means for determining whether the site is suitable for sampling physiological fluid for use in for an analyte concentration determination test based on the measured flow rate of physiological fluid at the site as analyte concentration determination is not of concern in the invention of Tiemann et al.

Douglas et al. fails to make-up for the deficiencies of Teimann et al. as Douglas et al. do not teach or suggest a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test nor means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate of physiological fluid at the site as Douglas et al. merely teaches methods and apparatus for sampling and analyzing body fluids.

The Examiner asserts that it would have been obvious to combine the lancing device of Douglas

et al. with the apparatus and method of Tiemann et al. to provide analyte concentration information as further information with which a physician may make a more accurate diagnosis. However, the Applicants respectfully submit that there would be no motivation to combine the lancing device of Douglas et al. with the apparatus and method of Tiemann et al. to provide analyte concentration information to a physician as Tiemann et al. is not concerned with the concentration of analytes at all. Rather, Tiemann et al. is concerned with tumor tissue characterization which is not the same as, nor concerned with, analyte concentration. Accordingly, for at least these reasons, Tiemann et al. in view of Douglas et al. fail to teach or suggest all of the claimed limitation of claims 8-10.

Claim 49, from which claims 61 and 63 depend, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate. However, Tiemann et al. do not teach a method for sampling physiological fluid for use in an analyte concentration determination test, nor do Tiemann et al. teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate at the site. Douglas et al. fail to make-up for the deficiencies of Teimann et al. Furthermore, as described above, there would be no motivation to combine the lancing device of Douglas et al. with the apparatus and method of Tiemann et al. to provide analyte concentration information to a physician as Tiemann et al. is not concerned with analyte concentration at all. Rather, Tiemann et al. is concerned with tumor tissue characterization which is not the same as, nor concerned with, analyte concentration. Accordingly, for at least these reasons, Tiemann et al. in view of Douglas et al. fail to teach or suggest all of the claimed limitation of claims 61 and 63.

Claim 65, from which claims 79 and 81 depend, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a determining step that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Tiemann et al. fail to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on determined fluid type. Douglas et al. fail to make-up for the deficiencies of

Teimann et al. Accordingly, for at least these reasons, Tiemann et al. in view of Douglas et al. fail to teach or suggest all of the claimed limitation of claims 79 and 81.

Claim 83, from which claims 99 and 101 depend, have been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate of physiological fluid and based on the determined fluid type at the site. However, Tiemann et al. fail to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach a method that includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate of physiological fluid and based on the determined fluid type at the site. Douglas et al. fail to make-up for the deficiencies of Teimann et al. Accordingly, for at least these reasons, Tiemann et al. in view of Douglas et al. fail to teach or suggest all of the claimed limitation of claims 99 and 101.

For at least the reasons described above, Tiemann et al. in view of Douglas et al. do not teach or suggest all of the claimed limitations of claims 8-10, 61, 63, 79, 81, 99 and 101. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 11, 23-26, 31, 60, 64, 70-72, 78, 82, 93-95, 98 and 102 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Osemwota.

Claim 11, depends from claim 1 and specifies means for automatically determining the concentration of at least one analyte in a physiological fluid. As described above, claim 1 has been amended to specify a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate of physiological fluid at the site. However, Tiemann et al. is generally directed to an apparatus for characterizing tumor tissue and do not teach or even suggest a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, as Tiemann et al. is concerned with tumor tissue characterization, Tiemann et al. do not teach or suggest means for determining whether the site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow

rate of physiological fluid at the site as analyte concentration determination is not of concern in the invention of Tiemann et al. Likewise Tiemann et al. do not teach or suggest means for automatically determining the concentration of at least one analyte in a physiological fluid as analyte concentration is not taught or even suggested in the invention of Tiemann et al. Osemwota fails to make-up for the deficiencies of Tiemann et al. as Osemwota merely describes a process for noninvasive determining hemoglobin concentration. For at least these reasons, Tiemann et al. in view of Osemwota fails to teach or suggest all of the claimed limitations of claim 11.

Claims 23-26 and 31 depend from claim 16. As described above, claim 16 has been amended to specify that the device is for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, that the at least one sample type characterization element determines whether a site includes arterial fluid, venous fluid or interstitial fluid, and also that the device includes means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Tiemann et al. fail to teach a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, a sample type characterization element that determines whether a site includes arterial fluid, venous fluid or interstitial fluid or means as claimed in these claims. Osemwota fails to make-up for the deficiencies of Tiemann et al. as Osemwota merely describes a process for noninvasive determining hemoglobin concentration. For at least these reasons, Tiemann et al. in view of Osemwota fail to teach or suggest all of the claimed limitations of claims 23-26 and 31.

Claims 60 and 64 depend from Claim 49 which, as described above, has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate. However, Tiemann et al. do not teach a method for sampling physiological fluid for use in an analyte concentration determination test, nor do Tiemann et al. teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on measured flow rate. Osemwota fails to make-up for the deficiencies of Tiemann et al. as Osemwota merely describes a process for noninvasive determining hemoglobin concentration. For at least these reasons, Tiemann et al. in view of Osemwota fail to teach or suggest all of the claimed limitations of claims 60 and 64.

Claims 70-72, 78 and 82 depend from claim 65 which, as described above, have been amended

to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a determining step that includes determining whether a potentially suitable site is suitable for the analyte concentration determination test based on the determined fluid type. However, Tiemann et al. fail to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on a determined fluid type. Osemwota fails to make-up for the deficiencies of Tiemann et al. as Osemwota merely describes a process for noninvasive determining hemoglobin concentration. For at least these reasons, Tiemann et al. in view of Osemwota fail to teach or suggest all of the claimed limitations of claims 70-72, 78 and 82.

Claims 93-95, 98 and 102 depend from claim 83 which, as described above, has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based the measured flow rate of physiological fluid and based on the determined fluid type at the site. However, Tiemann et al. fail to teach a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on flow rate and fluid type. Osemwota fails to make-up for the deficiencies of Tiemann et al. as Osemwota merely describes a process for noninvasive determining hemoglobin concentration. For at least these reasons, Tiemann et al. in view of Osemwota fails to teach or suggest all of the claimed limitations of claims 93-95, 98 and 102.

For at least the reasons described above, Tiemann et al. in view of Osemwota do not teach or suggest all of the claimed limitations of claims 11, 23-26, 31, 60, 64, 70-72, 78, 82, 93-95, 98 and 102. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Scharf.

Claims 19 and 20 depend from claim 16 which, as described above, has been amended to specify

a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, that the at least one sample type characterization element determines whether a site includes arterial fluid, venous fluid or interstitial fluid, and also that the device includes means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the determined fluid type. However, Tiemann et al. fail to teach a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test, a sample type characterization element that determines whether a site includes arterial fluid, venous fluid or interstitial fluid or means as claimed in these claims. Scharf fails to make-up for the deficiencies of Tiemann et al. as Scharf merely describes a pulse oximeter. For at least these reasons, Tiemann et al. in view of Osemwota fail to teach or suggest all of the claimed limitations of claims 19 and 20. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 40, 41, 47 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Toida et al.

Claims 40, 41, 47 and 48 depend from claim 36 which, as described above, has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate of physiological fluid and based on the determined fluid type at the site. However, both Tiemann et al. and Toida et al. fail to teach a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test or means for determining whether a site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on a measured flow rate and based on a determined fluid type. For at least these reasons, Tiemann et al. in view of Toida et al. fail to teach or suggest all of the claimed limitations of claims 40, 41, 47 and 48. As such, the Applicants respectfully request that the rejection be withdrawn.

Claim 38 was rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Toida et al. and further in view of Barker.

Claim 38 depends from claim 36 and as described above Tiemann et al. and Toida et al. either alone or in combination fail to teach or suggest all of the claimed limitations of claims 36. Furthermore, Barker fails to make-up for the deficiencies of Teimann et al. and Toida et al. as Barker merely teaches a fluid temperature sensor and fails to teach or suggest a device for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also fails to teach or suggest means for determining whether a site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on measured flow rate an fluid type at the site. For at least these reasons, Tiemann et al. in view of Toida et al. in further view of Barker fails to teach or suggest all of the claimed limitations of claim 38. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 43-46 was rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Toida et al. and further in view of Douglas et al.

Claim 43-46 depend from claim 36 which has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify means for determining whether the site is suitable for the analyte concentration determination test based on the measured flow rate of physiological sample at the site and based on the determined fluid type at the site. Claims 43-45 specify analyte concentration determination test strips and claim 46 specifies means for automatically determining the concentration of at least one analyte in the physiological fluid. However, both Tiemann et al. and Toida et al. fail to teach or suggest a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test or means as claimed. For example, Tiemann et al. teach a tumor characterization apparatus and method and Toida et al. teach a blood vessel imaging system, i.e., analyte concentration determination is not taught, suggested or otherwise required or needed in the inventions of Teimann et al. and Toida et al. Accordingly, these references fail to teach or suggest analyte concentration determination test strips as claimed in claims 43-45 and means for automatically determining the concentration of at least one analyte in the physiological fluid as claimed in claim 46.

Douglas et al. fail to make up for the deficiencies of Tiemann et al. and Toida et al. as Douglas fail to teach or suggest a method for determining the suitability of a site for sampling physiological fluid and means for determining whether a site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on a measured flow rate and based on a determined fluid

type. Furthermore, as noted above, there is no motivation to even combine the lancing device of Douglas et al with the apparatus and method of Tiemann et al. as asserted by the Examiner, as analyte concentration is not taught, suggested or otherwise required or needed in the invention of Teimann et al. For at least these reasons, Tiemann et al. in view of Toida et al. in further view of Douglas et al. fail to teach or suggest all of the claimed limitations of claim 43-46. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 50, 74 and 84 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Barker.

Claim 50 depends from claim 49 which has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate. However, Tiemann et al. do not teach or suggest a method for sampling physiological fluid for use in an analyte concentration determination test, nor do Tiemann et al. teach or suggest a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate at the site. Barker fails to make up for the deficiencies of Tiemann et al. For at least these reasons, Tiemann et al. in view of Barker fails to teach or suggest all of the claimed limitations of claim 50.

Claim 74 depends from claim 65 which has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a determining step that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on determined fluid type. However, Tiemann et al. fail to teach or suggest a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach or suggest a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on a determined fluid type. Barker fails to make-up for the deficiencies of Teimann et al. Accordingly, for at least these reasons, Tiemann et al. in view of Barker fails to teach or suggest all of the claimed limitation of claim 74.

Claim 84 depends from claim 83 which has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on measured flow rate of physiological fluid and based on determined fluid type at the site. However, Tiemann et al. fail to teach or suggest a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach or suggest a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on measured flow rate and fluid type at the site. Barker fails to make-up for the deficiencies of Teimann et al. Accordingly, for at least these reasons, Tiemann et al. in view of Barker fails to teach or suggest all of the claimed limitation of claim 84.

For at least the reasons described above, Tiemann et al. in view of Barker do not teach or suggest all of the claimed limitations of claims 50, 74 and 84. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 62, 80 and 98 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Rosenthal.

Claim 62 depends from claim 49 which has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify that the determining step includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate. However, Tiemann et al. do not teach or suggest a method for sampling physiological fluid for use in an analyte concentration determination test, nor do Tiemann et al. teach or suggest a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on the measured flow rate. Rosenthal fails to make up for the deficiencies of Tiemann et al. as Rosenthal fails to teach or suggest (1) a method for determining the suitability of a site for sampling physiological fluid, and (2) a method that includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on the measured flow rate. Furthermore, as noted above, there is no motivation to even combine the glucose meter of Rosenthal with the apparatus and method of Tiemann et al. as asserted by the Examiner, as analyte

concentration is not taught, suggested or otherwise required or needed in the invention of Teimann et al. For at least these reasons, Tiemann et al. in view of Rosenthal fail to teach or suggest all of the claimed limitations of claim 62.

Claim 80 depends from claim 65 which has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a determining step that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on determined fluid type. However, Tiemann et al. fail to teach or suggest a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach or suggest a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on determined fluid type. Rosenthal fails to make up for the deficiencies of Tiemann et al. as Rosenthal fails to teach or suggest (1) a method for determining the suitability of a site for sampling physiological fluid, and (2) a method that includes determining whether the potentially suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on determined fluid type. Furthermore, as noted above, there is no motivation to even combine the glucose meter of Rosenthal with the apparatus and method of Tiemann et al. as asserted by the Examiner, as analyte concentration is not taught, suggested or otherwise required or needed in the invention of Teimann et al. For at least these reasons, Tiemann et al. in view of Rosenthal fails to teach or suggest all of the claimed limitations of claim 80.

Claim 98 depends from claim 83 which has been amended to specify a method for determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test and also to specify a step of determining whether the potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on measured flow rate of physiological fluid and based on determined fluid type at the site. However, Tiemann et al. fail to teach or suggest a method of determining the suitability of a site for sampling physiological fluid for use in an analyte concentration determination test. Furthermore, Tiemann et al. fail to teach or suggest a method that includes determining whether a potentially suitable site is suitable for sampling physiological fluid for use in an analyte concentration determination test based on measured flow rate of physiological fluid and based on determined fluid type at the site. Rosenthal fails to make up for the deficiencies of Tiemann et al. as Rosenthal fails to teach or suggest (1) a method for determining the suitability of a site for sampling physiological fluid, and (2) a method that includes determining whether the potentially

suitable site is suitable for sampling physiological fluid for use in the analyte concentration determination test based on measured flow rate and determined fluid type. Furthermore, as noted above, there is no motivation to even combine the glucose meter of Rosenthal with the apparatus and method of Tiemann et al. as asserted by the Examiner, as analyte concentration is not taught, suggested or otherwise required or needed in the invention of Teimann et al. Accordingly, there is no motivation to include a step of determining the concentration of at least one analyte in the physiological sample in the invention of Tiemann et al., which step is taught in claim 98 For at least these reasons, Tiemann et al. in view of Rosenthal fails to teach or suggest all of the claimed limitations of claim 98.

For at least the reasons described above, Tiemann et al. in view of Rosenthal do not teach or suggest all of the claimed limitations of claims 62, 80 and 98. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 103-105 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Rose.

Claims 103 and 105 specify a kit that includes at least one device according to claims 1, 16 and 36 and instructions for using the at least one device. As described above, Teimann et al. do not teach or suggest a device according to claims 1, 16 and 36 or instructions for using a device according to claims 1, 16 or 36. Rose is cited solely for teaching a medical device instruction manual and as such does not teach or suggest a device according to claims 1, 16 and 36 or instructions for using a device according to claims 1, 16 and 36. For at least the reasons described above, Tiemann et al. in view of Rose do not teach or suggest all of the claimed limitations of claims 103-105. As such, the Applicants respectfully request that the rejection be withdrawn.

Claim 106 was rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Douglas et al. and in further view of Rose.

Claim 106 depends from claim 103 which specifies a kit that includes at least one device according to claims 1, 16 and 36 and instructions for using the at least one device. As described above, Teimann et al. do not teach or suggest a device according to claims 1, 16 and 36 or instructions for using a device according to claims 1, 16 and 36, nor do Douglas et al. Rose is cited solely for teaching a medical device instruction manual and as such does not teach or suggest a device according to claims 1, 16 and 36 or instructions for using a device according to claims 1, 16 and 36. For at least the reasons

described above, Tiemann et al. in view of Douglas et al. in further view of Rose do not teach or suggest all of the claimed limitations of claim 106. As such, the Applicants respectfully request that the rejection be withdrawn.

Claims 107 was rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Osemwota and in further view of Rose.

Claim 107 depends from claim 103 which specifies a kit that includes at least one device according to claims 1, 16 and 36 and instructions for using the at least one device. As described above, Teimann et al. do not teach or suggest a device according to claims 1, 16 and 36 or instructions for using a device according to claims 1, 16 and 36, nor does Osemwota. Rose is cited solely for teaching a medical device instruction manual and as such does not teach or suggest a device according to claims 1, 16 and 36 or instructions for using a device according to claims 1, 16 and 36. For at least the reasons described above, Tiemann et al. in view of Osemwota in further view of Rose do not teach or suggest all of the claimed limitations of claim 107 As such, the Applicants respectfully request that the rejection be withdrawn.

Claim 108 was rejected under 35 U.S.C. §103(a) as being unpatentable over Tiemann et al. in view of Barker and in further view of Rose.

Claim 108 specifies a kit that includes a plurality of devices selected from the devices according to claims 1, 16 and 36. As described above, Teimann et al. do not teach or suggest a device according to claims 1, 16 and 36, nor does Barker. The Examiner asserts that claim 108 includes instructions. However, the Applicants respectfully submit that instructions are not included in claim 108. Rose is cited solely for teaching a medical device instruction manual and as such does not teach or suggest a plurality of devices according to claims 1, 16 and 36. For at least the reasons described above, Tiemann et al. in view of Barker in further view of Rose do not teach or suggest all of the claimed limitations of claim 108. As such, the Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

In view of the remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, reference no. LIFE-045.

Respectfully submitted,
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Date: 1/26/04

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